

A CSR Backgrounder

New Data on NIH Peer Review of Grant Applications for Clinical Research

In August 2002, the Center for Scientific Review (CSR) at the National Institutes of Health (NIH) appointed [Dr. Theodore Kotchen](#) as Special Advisor on Clinical Research. Since that time, he has been involved in a number of activities, including gathering and analyzing data concerning the peer review of clinical research. Dr. Kotchen's article describing these studies— "[NIH Peer Review of Grant Applications for Clinical Research](#)"—appears in the February 18, 2004, issue of the *Journal of the American Medical Association*. This article seeks to assess how well clinical research grant applications fare in NIH peer review by analyzing data on the review outcomes for applications submitted by MDs and non-MDs and applications categorized as "clinical research" and "non-clinical research."

Data presented in the article show that MDs submitted 25.2% of the grant applications NIH received between 1997 and 2002, and MDs received 27.5% of the grants awarded during this period. However, in two grant cycles in 2002, median priority scores (254.0 vs. 244.0) and funding rates (23.9% vs. 28.1%) were slightly less favorable for R01 applications for clinical research than for laboratory research. The reasons for these slight differences in review outcomes are not clear. Factors related to both the preparation and the review of clinical research proposals may be involved, and one cannot ignore the fact that the pool of clinical researchers is relatively small and shrinking.

Dr. Kotchen and CSR will continue to study and monitor clinical review outcomes to assess factors that may affect them; however, CSR has already taken steps to address concerns related to both the preparation and review of clinical research applications:

- A strong statement of commitment was made when CSR appointed Dr. Kotchen to be its Special Advisor on Clinical Research. He is also Professor of Medicine and Epidemiology, and Associate Dean for Clinical Research at the Medical College of Wisconsin. At CSR, he has worked to advance activities to ensure that clinical applications are reviewed appropriately. In this capacity, he served as the lead author of the *JAMA* article. In addition, Dr. Kotchen has worked as CSR's liaison with the external clinical research community.
- A systematic [reorganization](#) of CSR's review groups is underway, with guidance from external experts, including representatives from the clinical research community. One of the major goals of this reorganization is to ensure that clinical applications are clustered so that they make up 25-30% of the applications in the study sections where they are reviewed. This reorganization is already being implemented and should be completed within 2-3 years.

- Six of CSR's study sections now deal almost exclusively with patient-oriented research, including two new study sections that review clinical oncology and clinical cardiovascular research proposals.
 - Increased numbers of clinical investigators will be recruited to fully implement CSR's reorganization.
 - Additional clinical study sections and clusters of clinical applications will be created as they are needed.
- Supplementary guidelines for clinical research applicants and reviewers were developed and posted on [CSR's Web site](#) to remind them of the factors that make a strong clinical research application.
 - Clinical professional societies have been invited to submit names of qualified clinical investigators for consideration as possible members of CSR study sections.
 - New flexible terms of service are being explored to allow more clinical investigators to be reviewers.
 - The priority scores CSR's study sections give to clinical and laboratory-oriented research applications are tracked and compared on an ongoing basis.
 - Additional studies of clinical review outcomes are ongoing and planned to better assess how well clinical applications fare in NIH peer review and to identify and address factors that may adversely effect the preparation or review of clinical applications.

The Center for Scientific Review organizes the peer review groups that evaluate the majority of grant applications submitted to the National Institutes of Health. CSR also receives all NIH and many Public Health Service grant applications and assigns them to the appropriate NIH Institutes and Centers and PHS agencies. Additional information on CSR is available on our Web site (<http://www.csr.nih.gov>) or by calling 301 435-1111.